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RESEARCH**

APPLICATION NUMBER:

74943

CHEMISTRY REVIEW(S)

1. CHEMIST'S REVIEW NO. 3

ANDA #74-943

3. NAME AND ADDRESS OF APPLICANT

Apotex USA Inc.
Attention: Marcy Macdonald
U.S. Agent for TorPharm Inc.
50 Lakeview Parkway, Suite 127
Vernon Hills, Illinois 60061

TorPharm Inc.
50 Steinway Boulevard
Etobicoke, Ontario
Canada M9W 6Y3

4. AF NUMBER OR LEGAL BASIS FOR ANDA SUBMISSION

Dilacor XR - Rhone-Poulenc Rorer Pharmaceutical Inc.
Expiration of Patent - TorPharm Inc. certifies that, in their opinion and to the best of their knowledge, US Patent Number 5,422,123 expiring June 6, 2012 will not be infringed by the manufacture, use or sale by TorPharm Inc. of Diltiazem XR Capsules 240 mg for which this application is submitted.

As required by section 505 (J) (2) (b) of the FDA and 21 CFR 314.94 (a) (12) (I) (a) (4) and 21 CFR 314.95, TorPharm Inc. states that notice has been sent to Rhone-Poulenc Rorer Pharmaceuticals Inc. the holder of the approved application for Dilacor XR 240 mg, and to Jagotec AG the record owner of US Patent Number 5,422,123.

Expiration of Exclusivity- No exclusivity date.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

Diltiazem XR Capsules

7. NONPROPRIETARY NAME

Diltiazem HCl Extended-Release Capsules USP.

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Firm:
August 16, 1996: Original Submission.
November 27, 1996: Amendment.
May 1, 1997: Amendment
January 29, 1998: Minor amendment
February 27, 98: Bio. amendment
March 6, 1998: Fax amendment
May 1, 1998: Telephone amendment
June 1, 1998: Telephone amendment

FDA:
February 14, 1997: Bio. deficiency letter
February 24, 1997: Deficiency letter
September 29, 1997: Bio. deficiency letter
November 6, 1997: Minor deficiency letter
March 25, 1998: Bio. letter
April 23, 1998: Telephone conversation
May 29, 1998: Telephone conversation

10. PHARMACOLOGICAL CATEGORY

Anti-hypertensive

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

NDA# N20092

DMF#

DMF#

DMF#

DMF#

DMF#

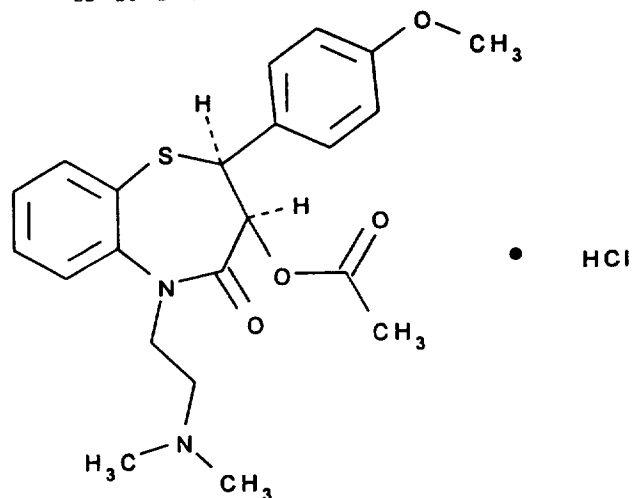
DMF#

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13. DOSAGE FORM
Capsules14. POTENCY
240 mg15. CHEMICAL NAME AND STRUCTUREDiltiazem Hydrochloride USP
 $C_{22}H_{26}N_2O_4S \cdot HCl$; M.W. = 450.98

(+)-5-[2-(Dimethyl amino)ethyl]-*cis*-2,3-dihydro-3-hydroxy-2-(*p*-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one acetate (ester) monohydrochloride. CAS [33286-22-5]

16. RECORDS AND REPORTS
N/A17. COMMENTS
The following deficiencies are noted in the review:

- None

18. CONCLUSIONS AND RECOMMENDATIONS
The application can be approved. The approvable letter will be issued.19. REVIEWER: Sema Basaran Ph.D. DATE COMPLETED: 2-9-98/5-11-98; 6.12.98 (revised)